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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,231

02/27/2004

Karl F. Popp

24948-X2

4828

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7590

07/02/2007

NATH & ASSOCIATES
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/787,231</p>	<p>Applicant(s)</p> <p align="center">POPP, KARL F.</p>	
	<p>Examiner</p> <p align="center">Lakshmi S. Channavajjala</p>	<p>Art Unit</p> <p align="center">1615</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-25-04; 9-30-04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt of IDS dated 9-30-04 and 5-25-04 is acknowledged.

Claims 1-63 are pending.

Claims 1 recites a method of treating bacterial disorder of skin comprising topically administering to the skin of a patient a composition comprising a storage-stable mixture of benzoyl peroxide and clindamycin. Dependent claims 2, 4 and 26 recite various bacterial disorders. Claim 28 is directed to a method of reducing or eliminating bacterial from skin with the above composition and dependent claims recite various genus and species of bacteria. Independent claim recites a method of treating bacterial disorder in a patient having sensitive skin, with the same composition as in claim 1. Claim 56 recites a method of treating bacterial infection, claim 58 directed to treating impetigo, claim 59 directed to folliculitis, claim 60 directed to erythrasma and claim 60 directed to a method of treating bacterial disorder in skin. All of the claims employ the same composition as in claim 1. Claim 60 requires the composition of claim 1 and an additional active agent.

Double Patenting

Claims 1-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/617191, and over claims 1-57 of copending Application No. 10/791862 in view US 6,150,381. Although the conflicting claims are not identical, they are not patentably distinct from each other. Instant claims are directed to a method of treated bacterial skin disorder or infection or the conditions associated with bacterial

infections using a composition comprising benzoyl peroxide and clindamycin. Both the co-pending sets of claims also recite the same composition. The claims of 10/617,191 also recite that the composition is used for bacterial skin conditions. 10/791,862 recite a method of treating rosacea with the same composition as that employed in the instant case. While 10/691,864 does not mention bacterial disorder, US 6150381 to Subbiah teaches that rosacea as a skin condition associated with acne and caused by propionic acne (col. 2-3). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to use the composition of 10/617191 or that of 10/691,864 to treat bacterial skin disorders of the instant because 10/617191 states that the composition is for treating bacterial skin disorders and US 6150381 teaches rosacea is a skin condition caused by bacterial infection of skin. A skilled artisan would have expected a successful treatment of skin conditions caused by bacterial infections with the composition of the above co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 10-16, 28, 29, 40-43, 46-57 and 61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,117,843 to Baroody et al (Baroody).

Baroody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months (col. 2, L 3-66). Baroody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and clindamycin is combined with a carrier, and further with a gelling agent such as Carbopol (col. 4, L 1-43). Table 1 of Baroody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5, which includes the pH of the instant claims. Thus, Baroody discloses the composition for the same purpose claimed in the instant application (claims 17-25). Baroody discloses applying the composition once or twice daily (col. 7, L 25-35). For claimed stability, Baroody shows that the composition is stable over a long period of time (table 7 and 8). Baroody does not specify the age group of patients that are treated with the composition. However, the examples show that the composition is highly effective against acne (col. 15-16) and therefore the composition of Baroody is effective against all the age groups (including those claimed). With respect to the viscosity, Baroody discloses that initial viscosity of benzoyl peroxide in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000. Table 1 teaches humectant in the composition, which meets the requirement of additional component of claims 61-63. For the claimed disorders, Baroody teaches that acne is caused by bacterial infection and hence meets the claimed disorders and primary or secondary infections claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9, 17-27, 30-39, 44-45 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Baroody et al (Baroody) in view of US 6,150,381 and Rosen et al (Pharmacotherapy, 1981).

Baroody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of claim 13, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. However, Baroody also recognize the same factors i.e., pH, viscosity etc., that affect the stability (result-affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long periods of time because the teachings of Baroody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin and employed

for the same purpose similar to the instant invention i.e., treatment of acne or other skin related conditions that need require benzoyl peroxide and clindamycin combination.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

For the claimed bacterial skin disorders, Baroody teaches that the composition is effective for acne but does not specifically state the bacterial conditions such as folliculitis, erythrasma etc.

US '381 teaches method of treating skin disorders caused by bacterial infections, including acne and describes the claimed conditions such as folliculitis, erythrasma as associated with acne (lines bridging col. 2-3). '381 teaches a combination of active agents such as sclareol or sclareolide compounds and also suggest adding benzoyl peroxide (claims), as effective against several bacterial species such as E. coli, S. aureus etc (example 1).

Rosen teaches that clindamycin is effective in treating acne vulgaris and also for conditions such as erythrasma, rosacea etc (abstract only).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to use the composition of Baroody for treating several bacterial skin disorders caused by acne bacterium i.e., folliculitis, rosacea etc., because '381 suggests benzoyl peroxide as effective for the bacterial skin disorders (above) and Rosen teaches clindamycin is effective for treating acne as well as the conditions such as folliculitis etc. Thus, a skilled artisan would have expected to inhibit not only acne

causing bacteria but also the skin conditions associated with the infection, with the composition of Baroody.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Baroody et al (Baroody) in view of Baltimore 9Pediatric Infectious Diseases, abstract (1985).

Baroody, discussed above fails to teach impetigo. Baltimore teaches antibiotic treatment for impetigo and suggests several antibiotics such as clindamycin, penicillin etc (abstract). Therefore, one of an ordinary skill in the art at the time of the instant invention would have readily recognized that clindamycin is effective against impetigo, in addition to being effective for treating acne. Accordingly, a skilled artisan would have employed the composition of Baroody in the treatment of impetigo.

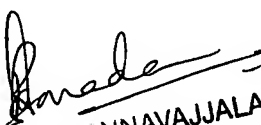
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
June 22, 2007



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER